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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/885,568	06/20/2001	John Jianhua Chen	S63.2-9515	8081
490 7590 03/16/2004 VIDAS, ARRETT & STEINKRAUS, P.A. 6109 BLUE CIRCLE DRIVE SUITE 2000 MINNETONKA, MN 55343-9185			EXAMINER HON, SOW FUN	
			ART UNIT 1772	PAPER NUMBER

DATE MAILED: 03/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/885,568

Applicant(s)

CHEN ET AL.

Examiner

Sow-Fun Hon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

Rejections Repeated

1. The 35 U.S.C. 102(b) rejection of claim 14 as being anticipated by Bland et al. has been repeated for reasons previously of record in the action mailed 10/06/03.

Withdrawn Rejections

2. The 35 U.S.C. 103(a) rejections in the action mailed 10/06/03 have been withdrawn due to the new rejections below.

New Rejections

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 1-6, 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rau et al. (WO 95/18647) in view of Zdrahala (previously cited US 5,248,305).

Rau et al. has a balloon catheter (column 1, lines 1-5) which can be of integral catheter shaft/balloon construction (column 14, lines 1-5) comprising a plurality of fibers to provide reinforcement (column 8, lines 55-65). The reinforcing fiber may comprise liquid crystal polymers (column 15, lines 1-5). Rau et al. teaches that the fibers (filaments) are aligned parallel along the structure (column 15, lines 5-10) which is interpreted to mean that the fibers are

oriented parallel to the longitudinal axis of the balloon (claim 12). This is a specific example of the fibers being distributed in a selected direction relative to the balloon axis (claim 1).

Rau et al. teaches that the liquid crystal polymers are rigid, rod-like (column 16, lines 25-30). The liquid crystal rods thus constitute cores of polymeric material which have a bulk elongation of less than 150 %, (claim 4). The liquid crystal rods are aligned parallel along the structure (column 15, lines 5-10) which means that they are oriented parallel to the longitudinal axis of the balloon. Being rigid, the liquid crystal core polymeric material has a bulk elongation less than the matrix material when oriented in the direction of the longitudinal axis. For good reinforcement, it would have been obvious to one of ordinary skill in the art to provide liquid crystal polymer with greater tensile strength than the thermoplastic polymer matrix (claim 1), as evidenced by Zdrahala.

Zdrahala discloses that high tensile strength is highly desirable for liquid crystal polymer reinforcements of thermoplastics (column 3, lines 10-25).

Rau et al. teaches that the shaft may be composed of a blend of polymer (polyimide) and liquid crystal (column 16, lines 20-25), and that when the balloon is integral with the shaft (column 14, lines 10-15), the matrix polymer is thermoplastic polymer (polyimide). Thus the balloon is of the same composition as the shaft when it is integral with the shaft, and is composed of a blend of thermoplastic polymer and liquid crystal as well. As a blend, the liquid crystal polymer fiber reinforcement cores are coextruded with the matrix thermoplastic polymer material (column 14, lines 10-20) (claim 3).

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Rau et al. teaches that the balloon may comprise a plurality of laminate layers (column 10, lines 10-20), at least one of which comprises said polymer matrix material and said fibers (reinforcing components) (column 14, lines 25-30).

Rau et al. fails to teach that the liquid crystal polymer fibers are distributed in the matrix material helically relative to the balloon axis, or that the fibers have a diameter of from 0.01 to about 10 microns.

Zdrahala teaches an extruded catheter tubing which exhibits stiffness in the longitudinal direction as well as rotational stiffness and both may be varied along the length of the tubing (column 1, lines 55-70 and column 2, lines 1-5). The composition contains from 5 to 35 weight percent of the liquid crystal polymer, and the matrix of the blend may be composed of polyurethanes, polyesters and copolyester elastomers which are softer materials than the liquid crystal polymer (column 4, lines 15-35) so that they are either compliant or semi-compliant. The liquid crystal fibers are distributed in the matrix material helically relative to the balloon axis (separate phase of liquid crystal plastic forms helical extending, separate fibrils within the extruded tubing with the fibers (fibrils) being dispersed in the structural plastic matrix) (column 5, lines 1-15). The fibers are thus cores of polymeric material coextruded with the matrix material (column 6, lines 35-22).

Zdrahala thus demonstrates that it would have been obvious to one of ordinary skill in the art to have distributed the liquid crystal polymer fibers in the matrix material helically relative to the balloon axis of Rau et al. in order to provide some rotational stiffness to control the radial expansion of the balloon.

Zdrahala teaches that the fibers (fibrils) exhibit an aspect ratio of about 10 to 300, the aspect ratio being defined by the length of the fiber divided by its diameter (column 5, lines 15-25). Thus in the absence of a showing of unexpected results, the claimed range of the LCP (liquid crystal polymer) fiber diameter of from 0.01 to about 10 microns is the result of routine experimentation.

5. Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rau et al. in view of Zdrahala as applied to claims 1-6, 9-12 above, and further in view of Bland et al. (previously cited US 5,427,842).

Rau et al. has been discussed above, and teaches the balloon may comprise a plurality of laminate layers (column 10, lines 10-20), at least one of which comprises said polymer matrix material and said fibers (reinforcing components) (column 14, lines 25-30). Raul et al., however, fails to teach that the laminate layers comprise an alternating series of fiber-containing and fiber-free layers.

Bland et al. teaches that angioplasty balloons require stiff tear-resistant films since they cannot tear during use, and must inflate to a controlled size and should not stretch to a larger size (column 1, lines 45-50). Bland et al. teaches a tear-resistant multilayer film comprising alternating layers of relatively stiff and ductile polymeric materials (column 1, lines 10-15). The tear resistant film comprises more than 5 layers and which overlaps the claimed range of at least 7 laminate layers (column 3, lines 30-40).

Bland et al. thus demonstrates that it would have been obvious to one of ordinary skill in the art to have provided the balloon of Rau et al. with laminate layers comprising an alternating

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series of fiber-containing and fiber-free layers in order to obtain an angioplasty balloon with improved tear resistance and controlled inflation dimension.

6. Claims 15-19, 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bland et al. in view of Rau et al.

Bland et al. teaches that angioplasty balloons require stiff tear-resistant films since they cannot tear during use, and must inflate to a controlled size and should not stretch to a larger size (column 1, lines 45-50). Bland et al. teaches a tear-resistant multilayer film comprising alternating layers of relatively stiff and compliant (ductile) polymeric materials (column 1, lines 10-15). The tear resistant film comprises more than 5 layers which encompasses the claimed range of 7 to 50 laminate layers (column 3, lines 30-40).

Bland et al., however, fails to teach that the stiff layers are composed of a blend of a matrix polymer material and an LCP polymer.

Rau et al. has a balloon catheter (column 1, lines 1-5) which can be of integral catheter shaft/balloon construction (column 14, lines 1-5) comprising a plurality of fibers to provide reinforcement (column 8, lines 55-65). The reinforcing fiber may comprise liquid crystal polymers (column 15, lines 1-5). Rau et al. teaches that the fibers (filaments) are aligned parallel along the structure (column 15, lines 5-10) which is interpreted to mean that the fibers are oriented parallel to the longitudinal axis of the balloon (claim 12). This is a specific example of the fibers being distributed in a selected direction relative to the balloon axis (claim 1).

Rau et al. teaches that the liquid crystal polymers are rigid, rod-like (column 16, lines 25-30). The liquid crystal rods thus constitute cores of polymeric material which have a bulk elongation of less than 150 %, (claim 4). The liquid crystal rods are aligned parallel along the

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structure (column 15, lines 5-10) which means that they are oriented parallel to the longitudinal axis of the balloon. Being rigid, the liquid crystal core polymeric material has a bulk elongation less than the matrix material when oriented in the direction of the longitudinal axis.

Rau et al. teaches that the balloon may comprise a plurality of laminate layers (column 10, lines 10-20), at least one of which comprises said polymer matrix material and said fibers (reinforcing components) (column 14, lines 25-30). The layers may all carry the same polymer material (thermoplastic polyimide) so that the single polymer material and the matrix polymer material are the same (claim 16). In Fig. 16, Rau et al. shows inner and outer layers of thermoplastic polymer surrounding an intermediate layer comprising a blend (column 5, lines 15-20). When the catheter balloon/shaft is integral, the balloon has the same construction as the shaft, and hence the alternating layers of single polymer (A) and blend of polymer and liquid crystal fiber (B). The single polymer layers are thicker than the blend layer. Thus the claimed ratio A/B of the total thickness of the two types of layers (A) and (B) respectively, of from about 5 to about 15 (claim 18), and of from about 8 to about 10 (claim 19), is the result of routine experimentation, in the absence of a clear demonstration of unexpected results.

Therefore it would have been obvious to one of ordinary skill in the art to have provided the balloon of Rau et al. with 7 to 50 laminate layers comprising an alternating series of stiff fiber-containing and compliant fiber-free layers as taught by Bland et al. in order to obtain an angioplasty balloon with improved tear resistance and controlled inflation dimension.

7. Claims 20, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bland et al. in view of Rau et al. as applied to claims 15-17, 21 above, and further in view of Zdrahala.

Bland et al. has been discussed above and teaches a catheter balloon comprising at least 5 laminate layers which encompasses the claimed range of from 7 to 50 laminate layers of polymer material. Rau et al. teaches a catheter balloon which has an integral balloon/shaft structure comprising alternating layers of single polymer and polymer/liquid crystal polymer fiber blend.

Both Bland et al. and Rau et al. fail to teach the amount of liquid crystal polymer fiber, or that the polymer matrix is polyamide.

Zdrahala teaches that the catheter tubing may be made out of 10 to 40 weight percent of liquid crystal polymer, which overlaps the claimed range of from about 5 to about 25 % by weight percent (claim 20), and that the compliant (softer) matrix polymer material may be polyamides (column 4, lines 20-30).

Zdrahala thus demonstrates that it would have been obvious to one of ordinary skill in the art to have used from about 5 to about 25 % by weight of liquid crystal polymer in a polyamide matrix as the blend in the balloon of Rau et al. in order to obtain an alternate catheter balloon.

Response to Arguments

8. Applicant's arguments with respect to claims 1-13, 15-22 have been considered but are moot in view of the new ground(s) of rejection.
9. Applicant's arguments with respect to claim 14 as being anticipated by Bland et al. have been considered but not deemed persuasive for the reasons set forth below.
10. Applicant argues that specifically Bland et al. describe and claim the use of the films in security control laminates, and that while angioplasty balloons are mentioned in the background

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of the invention, there is no specific teaching as to making angioplasty balloons, and how many layers would be employed in making angioplasty balloons.

Applicant is respectfully apprised that Bland et al. teaches that angioplasty balloons require stiff tear-resistant films since they cannot tear during use, and must inflate to a controlled size and should not stretch to a larger size ('842, column 1, lines 45-50). Bland et al. teaches a tear-resistant multilayer film comprising alternating layers of relatively stiff and compliant (ductile) polymeric materials ('842, column 1, lines 10-15). The teaching of the use of stiff tear-resistant films in angioplasty balloons right after the introduction of the tear-resistant multilayer film of the invention clearly anticipates the use of the tear-resistant film of Bland et al. in an angioplasty balloon. Bland et al. then teaches that the tear resistant film comprises more than 5 layers, which encompasses the claimed range of from 7 to 50 laminate layers ('842, column 3, lines 30-40). Although Bland et al. does not teach how to make angioplasty balloons, and how many layers would be employed in making angioplasty balloons, Bland et al. teaches how to make the film, how many layers would be employed in making the film, and suggests that the film may be used to make tear-resistant angioplasty balloons. Thus the claim recitation of "a balloon for a medical device comprising from 7 to 50 laminate layers of polymer material" is clearly met.


Any inquiry concerning this communication should be directed to Sow-Fun Hon whose telephone number (571)272-1492. The examiner can normally be reached Monday to Friday from 9:00 AM to 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on (571)272-1498. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SH
Sow-Fun Hon
03/04/04


HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

3/5/04